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Human medicines in 2024

16 January 2025

114 new medicines recommended for approval; 46 had a new active substance

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In 2024, EMA recommended 114 medicines for marketing authorisation. Of these, 46 had a new active substance which had never been authorised in the European Union (EU) before. Among these are a number of medicines that stand out due to their contribution to address public health needs or the innovation they represent. The Agency recommended the first medicine to treat early Alzheimer's disease, the first needle-free and smaller form of adrenaline to treat allergic reactions, the first treatment for tumours associated with von Hippel-Lindau disease, and two new antibiotic medicines for the treatment of certain severe infections.

EMA also recommended several new vaccines, including one to protect against Chikungunya disease and a new mRNA vaccine against lower respiratory tract disease caused by respiratory syncytial virus (RSV), and extended the use of an mpox vaccine to protect adolescents from 12 to 17 years of age.

As in previous years, cancer was the strongest therapeutic area, with 28 recommendations for oncology products. There were also 28 recommendations for new biosimilar products, covering a wide range of diseases, including several types of cancer, osteoporosis, macular degeneration, and diseases that involve an abnormal immune response like plaque psoriasis, ulcerative colitis and Crohn's disease. This is good news for patients, as biosimilars make treatments more accessible and can provide broader access to potentially life-changing medicines.

The overview of the 2024 key recommendations published today includes figures on the authorisation of medicines and a selection of new treatments that represent significant progress in their therapeutic areas.

Once a medicine is authorised by the European Commission and prescribed to patients, EMA and the EU Member States continuously monitor its quality and benefit-risk balance and take regulatory action when needed. Measures can include a change to the product information, the suspension or

withdrawal of a medicine, or a recall of a limited number of batches. An overview of some of the most notable safety-related recommendations is also included in the document linked below.

Related documents

Human medicines in 2024

English (EN) (20.25 MB - PDF)
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